



90 Orville Drive, Bohemia, NY 11716-2510 ■ Phone: (631) 567-9500 ■ Fax: (631) 218-7480

1034 04 29 11:16

DEC 21 2004

Office of Nutritional Products/Labeling & Dietary  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW (HFS-810)  
Washington, D.C. 20204

October 26, 2004

DEC 22 2004

Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that NBTY Inc. is using the following statements on the St. John's Wort supplement under the Giant Eagle brand name.

- Supports/Promotes a positive mood.
- Used for centuries as a tonic, St. John's Wort helps promote a positive mood.
- St. John's Wort promotes a positive mood and a healthy emotional balance.

The above statements are accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

Angelica S. Vrablic, Ph.D.  
Manager, Nutrition Research

ASV/mb

97S 0162

LET

15216

90444